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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,853	12/30/2003	Carl J. Wheeler	1530.0260002	6433
26111 7590 01/29/2009 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				
EXAMINER				
ROYDS, LESLIE A				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/748,853

Applicant(s)

WHEELER, CARL J.

Examiner

Leslie A. Royds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-90 is/are pending in the application.
- 4a) Of the above claim(s) 65, 66, 75-82 and 88-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64, 67, 69, 70, 83 and 84 is/are rejected.
- 7) ☒ Claim(s) 68, 71-74, 85-87 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 64-90 are presented for examination.

Applicant's Amendment filed November 6, 2008 has been received and entered into the present application.

Claims 64-90 remain pending. Claims 64, 67-74 and 83-87 remain under examination and claims 65-66, 75-82 and 88-90 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 64, 71 and 74 are amended.

Applicant's arguments, filed November 6, 2008, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claims 68, 71-74 and 85-87 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

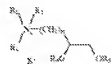
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 64, 67, 69-70 and 83-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nantz et al. (U.S. Patent No. 5,869,715; Issued 1999, Filed September 1995) in view of Felgner (WO

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91/17424; 1991), each already of record, for the reasons of record set forth at p.5-7 of the previous Office Action dated August 6, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 64 remains properly included in the instant rejection because Nantz et al. teaches cationic lipid compounds that are functional to bind and transport polynucleotides, polypeptides, pharmaceutically substances and other biologically active species through membrane barriers (col.1, 1.6-



9), wherein the cationic compounds are of the following chemical structure:

wherein R_4 and R_3 may each be, *inter alia*, alkyl; m is 1-10; R_1 and R_2 may each be, *inter alia*, alkyl; X is an anion; and R_2 may be, *inter alia*, an acyloxy containing alkyl group (col.3, 1.42-67). Such cationic lipid compounds disclosed by Nantz et al. correspond to Applicant's instantly claimed compounds, wherein R_1 and R_2 are each independently a linear or branched, unsubstituted or substituted C1-C23 alkyl; n is 1-6; R_3 and R_4 are each independently a linear or branched, unsubstituted or substituted C1-C23 alkyl; m is 1-10; Z is oxygen; and R_6 is hydrogen or equivalent to R_1 , R_2 , R_3 or R_4 (i.e., in this case, R_6 may be linear or branched, unsubstituted or substituted C1-C23 alkyl). Though Applicant has amended instant claim 64 to remove the option of Z to be CR_2R_6 , the claims still provide for Z to be oxygen, which, when Nantz et al. contains an acyloxy containing alkyl group as, e.g., R_2 , meets Applicant's instant claims.

Applicant traverses the instant rejection, stating that Nantz et al. discloses three preferred compounds of the invention wherein the cytofectin contains a nitrogen substituted with a hydroxylated alkyl (Compound A, col.4, 1.23-30), an ether containing alkyl (Compound B, col.5, 1.42-50) and a halogenated alkyl (Compound C, col.7, 1.10-20) and further submits that the preference for these three compounds is supported by the disclosures of generalized synthetic schemes for these compounds at col.4-13. Applicant asserts that the abstract and summary of the invention fails to disclose cytofectins wherein a quaternary nitrogen is substituted with acyl or acyloxy containing alkyl groups and alleges that

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Nantz et al. fails to suggest a method of making or using such compounds. Still further, Applicant states that the claims are amended to exclude compounds wherein the nitrogen can contain an acyl containing alkyl group by removing CR_7R_8 from the list of substituents of "Z". Applicant asserts that Nantz et al. fails to teach or suggest a compound with a functional group corresponding to $COOR'$ as instantly claimed and, because of this fact, the combination of Nantz et al. with Felgner used to render the instant invention obvious is moot.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant appears to be of the persuasion that, because Nantz et al. discloses three preferable compounds that do not contain the acyloxy containing alkyl group, this somehow constitutes a complete lack of teaching of the claimed compound and/or constitutes a teaching away from the instantly claimed compound. This is not persuasive. A preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Please see MPEP at §2123, which states, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments." Thus, the fact that other compounds may be exemplified, claimed and/or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, a compound of identical structure to those within the genus of compounds instantly claimed. Moreover, Applicant is reminded that there is no legal requirement that a reference *must exemplify or claim or prefer* a particular embodiment in order to constitute a teaching of the same. A reference will constitute a teaching so long as the disclosure clearly describes and enables

such an embodiment, which, in the present case, such description is clearly found in Nantz et al.

Compounds of the formula described in Nantz et al. wherein R1, R2 or R3 may be, *inter alia*, an acyloxy containing alkyl group is clearly an embodiment contemplated, and disclosed, by Nantz et al. as evidenced by his teaching at col.3 l.42-67. The fact that the reference may teach embodiments that differ from Applicant's own invention does not negate, or teach away from, the teachings of the reference as a whole and what the reference as a whole would have reasonably suggested to one having ordinary skill in the art at the time of the invention. Furthermore, picking and choosing elements from a reference, such as, in the instant case, that the abstract and summary of the invention fail to disclose that the quaternary nitrogen is substituted with an acyl or acyloxy containing alkyl group, that differ from those upon which the Examiner relies in support of the rejection as a means for discounting the case of *prima facie* obviousness made by the Examiner is not persuasive when Applicant does not clearly acknowledge and address the pertinent teachings of the reference upon which the rejection is based, specifically, the disclosure found at col.3, l.42-67, which clearly teaches the compounds discussed in the body of the previous rejection.

Secondly, Applicant also alleges that the reference to Nantz et al. does not teach how to make or use cytofectin compounds wherein the quaternary nitrogen is substituted with an acyl or acyloxy containing alkyl group. This is unpersuasive for the following reasons: (1) Nantz et al. very clearly provides numerous methods of synthesis in the body of the disclosure for various permutations of the disclosed compounds. Please see Nantz et al. at cols.4-13. Furthermore, the various methods of synthesis are disclosed in a generalized schematic to cover more than one species of compounds to be made such that the synthetic methods disclosed are not so limited to only a specific number of species and to the exclusion of the compounds upon which the rejection relies. Moreover, Nantz et al. explicitly states that, "The subject synthesis schemes present opportunities for a widely flexible array of approaches to synthesizing related amine cationic transport molecules." (col.12, l.52-54) In other words, the methods

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provided are simply exemplary and modifications thereof are understood to be within the realm of knowledge of one of ordinary skill in the medical and chemical arts. Please also see MPEP §2164.01(b), which states, " As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)." It is clear that Nantz et al. discloses even more than one method for making the invention disclosed and claimed therein and, thus, provides adequate enabling direction to the skilled artisan as to how to make the disclosed compounds; and (2) Nantz et al. also is replete with uses of the disclosed compounds. Please see, e.g., at least col.1, 1.6-9, which teaches that the genus of cationic compounds disclosed therein are lipid compounds that are functional to bind and transport polynucleotides, polypeptides, pharmaceutical substances and other biologically active species through membrane barriers. Accordingly, the contention that Nantz et al. fails to teach how to make and/or use the disclosed compounds is clearly erroneous in view of what is taught within the four corners of the reference and, thus, fails to be persuasive in establishing nonobviousness.

Thirdly, Applicant states that the claims are amended to exclude compounds wherein the nitrogen can contain an acyl containing alkyl group by removed CR_4R_5 from the list of substituents of "Z" and, thus, Nantz et al. fails to teach the instantly claimed compounds because the instant compounds have a "carboxy" group, not an "acyloxy" group as disclosed by Nantz et al. This is clearly unpersuasive. An "acyloxy" group as disclosed by Nantz et al. is understood to be an acyl group (i.e., $R-(C=O)$) bound to an oxygen, which clearly meets Applicant's claimed limitation of R_5 wherein Z is an oxygen atom and R_6 may be, *inter alia*, alkyl, etc. Please see p.3 of the instant claims. The allegation that Nantz et al. fails to provide for a functional group corresponding to $COOR'$ as required by the instant claims is incorrect because the teaching of an acyloxy group very clearly *does* provide for the group $COOR'$ and Applicant has failed to provide evidence otherwise showing that an acyloxy group as taught by Nantz et al. does not

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meet this limitation. Absent such evidence, the remarks to this effect are not found persuasive.

Fourthly, and lastly, though Applicant argues that the combination of Nantz et al. with Felgner is moot because Nantz et al. does not teach the claimed compounds, such a remark is also clearly unpersuasive in establishing nonobviousness of the instant claims because Nantz et al. does, in fact, demonstrate that the compounds of the instant claims are taught for the reasons elucidated *supra*. Accordingly, in the absence of any further remarks regarding the combination of Nantz et al. with Felgner, it is maintained that the combination of such references as set forth in the previous Office Action continues to render the claimed subject matter *prima facie* obvious for the reasons disclosed therein.

For these reasons presented *supra*, and those previously made of record at p.5-7 of the office action dated August 6, 2008, rejection of claims 64, 67, 69-70 and 83-84 remains proper.

Conclusion

Rejection of claims 64, 67, 69-70 and 83-84 is proper.

Claims 68, 71-74 and 85-87 are objected to for depending from a rejected base claim.

Claims 65-66, 75-82 and 88-90 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

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advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

January 23, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614